



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: SEP 21 2004
From: Interdisciplinary Scientist Division of Dietary Supplement Programs, Office of
Nutritional Products, Labeling and Dietary Supplements, HFS-810
Subject: 75-Day Premarket Notification of New Dietary Ingredients
To: Dockets Management Branch, HFA-305

Subject of the Notification: Kakadu Plum Concentrate
Firm: Access Business Group, LLC
Date Received by FDA: 6/24/2004
90-Day Date: 9/22/2004

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and
Cosmetic Act, the attached 75-day premarket notification and related correspondence for the
aforementioned substance should be placed on public display in docket number 95S-0316 as
soon possible since it is past the 90-day date. Thank you for your assistance.

Lanya L. Jackson, IDS

95S-0316

RPT248



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

SEP 3 2004

Diane B. McColl
Hyman, Phelps and McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

Dear Ms. McColl:

This is to inform you that the notification that you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on June 24, 2004. Your notification concerns the substance "Kakadu Plum Concentrate" that you intend to market as a new dietary ingredient.

According to the notification, "ABG anticipates that its "Kakadu Plum Concentrate" will be used as a source of Vitamin C in various dietary supplement products, such as multi-vitamin multi-mineral supplements and iron supplements. Such supplement products would be expected to provide 10-800 mg "Kakadu Plum Concentrate" per day under the ordinary conditions of intended use of the supplement."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

Federal regulations found at 21 CFR 190.6 specify the requirements for a pre-market notification on a new dietary ingredient. The notification you sent us concerning your new dietary ingredient, "Kakadu Plum Concentrate" did not comply with the requirements of 21 CFR 190.6 and is incomplete.

Your notification did not clearly identify the source of your proposed new dietary ingredient, "Kakadu Plum Concentrate". It is unclear to us whether you are using fruit from either *Terminalia ferdinandiana* Exell or *Terminalia latipes* Benth., or a combination of both as the source of your proposed new dietary ingredient, "Kakadu Plum Concentrate". For example, in your cover-letter dated June 18, 2004, you state "this new dietary ingredient notification" is "for Kakadu Plum (*Terminalia ferdinandiana*) Concentrate." However, on page 1 section 1.3 of the notification under the heading of "Scientific Names", you include two Latin binomials, "*Terminalia ferdinandiana*, and *Terminalia latipes*". Your letter dated June 22, 2004, contains "the Latin binomial names *Terminalia ferdinandiana* and *Terminalia latipes*". Since the botanical source(s) of your product "Kakadu Plum Concentrate" is unclear, FDA did not review the history of use information or the safety data.

FDA is unable to determine whether the notification provides an adequate basis for conclusion that the dietary supplement will reasonably be expected to be safe because the information you have provided is incomplete. If you market your product without submitting a new notification that meets the requirements of 21 CFR 190.6 or market your product less than 75 days after submitting such a notification, your product is considered adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of June 24, 2004. After the 90-day date, the notification will be placed on public display at FDA's Division of Docket Management in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Linda Pellicore, Ph.D., at (301) 436-2375.

Sincerely yours,

A handwritten signature in cursive script that reads "Linda S. Pellicore".

for Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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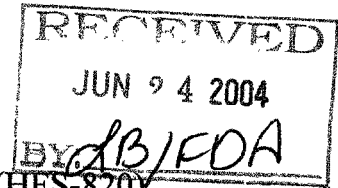
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DIRECT DIAL (202) 737-4291

June 18, 2004



Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

Re: New Dietary Ingredient Submission for Kakadu Plum Concentrate

Dear Sir/Madam:

Pursuant to Section 8 of the Dietary Supplement Health and Education Act of 1994, Access Business Group LLC (ABG), located at 7575 Fulton St. East, Ada, Michigan 49355, submits this new dietary ingredient notification to the Food and Drug Administration (FDA) for Kakadu Plum (*Terminalia Ferdinandiana*) Concentrate.

ABG intends to market Kakadu Plum Concentrate as a dietary ingredient in dietary supplements. Specifically, ABG intends to introduce a Kakadu Plum Concentrate, containing no less than 15% Vitamin C, for use as a natural source of Vitamin C. The fresh fruit and drinks prepared from the Kakadu Plum are traditional foods of some aboriginal populations in the north and northwestern parts of Australia. The greatest use for the Kakadu Plum at present is in gourmet jams and sauces served in restaurants, airlines and hotels, or sold as specialty foods. The Australian Therapeutic Goods Administration (TGA) approved Kakadu Plum (dry fruit flesh and aqueous extracts of the fruit flesh) for food and dietary supplement use in December of 2003.

88746

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Office of Nutritional Products, Labeling and Dietary Supplements

June 18, 2004

Page 2

ABG's Kakadu Plum Concentrate is an extract of the Kakadu Plum that has been concentrated and spray-dried to a powder form. ABG anticipates that its Kakadu Plum Concentrate will be used as a source of Vitamin C in various dietary supplement products, such as multi-vitamin multi-mineral supplements, Vitamin C supplements, antioxidant supplements, Vitamin C with flavonoids supplements and iron supplements. Such supplement products would be expected to provide 10 - 800 mg Kakadu Concentrate per day under the ordinary conditions of intended use of the supplement.

Attached is a discussion of basis upon which ABG has concluded that its Kakadu Plum Concentrate, when used under the ordinary conditions of intended use as a source of Vitamin C in dietary supplements, does not present an unreasonable or significant risk to safety and is reasonably expected to be safe. Included in the attachment are chemistry, manufacturing, and stability information; a description of the intended use; and a copy of the confidential TGA report on ABG's Kakadu Plum Concentrate.

Sincerely,



Diane B. McColl
Counsel to Access Business Group LLC

DBM/lmr
Enclosure



Australian Plant Name Index (APNI)

Combretaceae R.Br.

***Terminalia ferdinandiana* Exell**

Exell, A.W. (1935) *Journal of Botany, British and Foreign*: 263

basionym: ***Terminalia edulis* F.Muell.** nom. illeg.

Comment: *nom. nov.*

Byrnes, N. (1977) *Contributions from the Queensland Herbarium* 20: 1-72 (42-44)

synonym: ***Terminalia edulis* F.Muell.** nom. illeg.

Pedley, L. in George, A.S. (Ed) (1990), *Flora of Australia* 18: 255-293 (286, 326)

Map CANB collections.

CAVP: NT: DDG, DVR,; QLD: QCO,; WA: WDM, WFI, WGA



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Type: "N. Australia. Victoria River, Bynoe."

Comment: Base name for *Myrobalanus latipes* (Benth.) Kuntze.

Kuntze, C.E.O. in Kuntze, C.E.O. (1891), *Revisio Generum Plantarum* 1: 237

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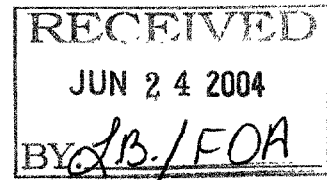
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*NOT ADMITTED IN DC

June 22, 2004

BY MESSENGER

Vickie Lutwak
Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740



Re: New Dietary Ingredient Submission (NDI) for Kakadu Plum Concentrate

Dear Vickie:

As requested, enclosed is another copy of the NDI submitted by Access Business Group LLC for its Kakadu Plum Concentrate. Also enclosed are three copies of references from the Australian Plant Name Index (APNI), including authors, for the Latin binomial names *Terminalia ferdinandiana* and *Terminalia latipes* provided in the NDI. As I mentioned in our conversation, I will be out of the office on sabbatical from June 29 through July 30, 2004. Please contact Paul Hyman (e-mail: pmh@hpm.com; phone: 202-737-4281) if any questions arise during my absence.

Sincerely,

A handwritten signature in cursive script that reads "Diane B. McColl".

Diane B. McColl

Enclosure
DBM/hfm

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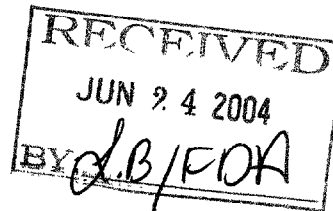
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June 18, 2004

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
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5100 Paint Branch Parkway
College Park, Maryland 20740

Re: New Dietary Ingredient Submission for Kakadu Plum Concentrate

Dear Sir/Madam:

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ABG intends to market Kakadu Plum Concentrate as a dietary ingredient in dietary supplements. Specifically, ABG intends to introduce a Kakadu Plum Concentrate, containing no less than 15% Vitamin C, for use as a natural source of Vitamin C. The fresh fruit and drinks prepared from the Kakadu Plum are traditional foods of some aboriginal populations in the north and northwestern parts of Australia. The greatest use for the Kakadu Plum at present is in gourmet jams and sauces served in restaurants, airlines and hotels, or sold as specialty foods. The Australian Therapeutic Goods Administration (TGA) approved Kakadu Plum (dry fruit flesh and aqueous extracts of the fruit flesh) for food and dietary supplement use in December of 2003.

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NDI Submission for Kakadu Plum Concentrate

1.0 Product Description

1.1 Kakadu Plum

The Kakadu plum is a fruit from a tree localized in the northern regions of the Northern Territories, Queensland, and Western Australia. The fruit consists of a hard, woody seed covered by a layer of edible flesh. The Kakadu plum is harvested from early March through June, depending on the severity and extent of the monsoon season.

Access Business Group L.L.C.'s (ABG's) Kakadu Plum Concentrate is a spray-dried concentrate of a water extract of Kakadu plums. ABG's product contains no less than 15% Vitamin C, and may contain as much as 45% Vitamin C. The product was approved by the Therapeutics Goods Administration (TGA) in December 2003. See *Commonwealth of Australia Gazette* notice in Appendix 1.

1.2 Common Names

Kakadu Plum, Billy Goat Plum, Green Plum, Salty Plum, Wild Plum, murunga (Aboriginal), manmohpan (Aboriginal), marnybi (Aboriginal).

1.3 Scientific Names

Terminalia ferdinandiana, and *Terminalia latipes* to a minor extent. Family name is Combretaceae.

1.4 Physical and Chemical Properties

Aspect: Dry Powder

Color: Ranges from medium-tan to dark-tan/light brown.

Odor: Slight caramelized aroma.

Taste: Tart, with slight salty, astringent, and bitter components.

Solubility: Water Soluble

Particle Size: Minimum 100% through a USSS 40-mesh sieve.

Moisture: Maximum 5% (LOD)

Hygroscopicity: Hygroscopic; should be packaged and stored accordingly.

Vitamin C content: $\geq 15\%$

1.5 Product Specifications

ABG's Kakadu Plum Concentrate contains no less than 15% Vitamin C. The product meets appropriate food grade specifications. Further information regarding the specifications is provided in the confidential TGA report in Appendix 2.

1.6 Method of Manufacture

The fruit is harvested in the greater Darwin areas and is essentially free of extraneous materials including leaves, stems and all non-Kakadu Plum materials. The fruit is placed in a freezer at less than or equal to -20°C and kept at that temperature until processing.

The manufacturing process consists of milling, water extraction and enzyme treatment, pressing to recover juice, filtering to remove particulate matter, pasteurizing, and spray drying. All processing aids are either United States Pharmacopoeia (USP) or food grade substances permitted for use in the production of foods and food ingredients. The extraction ratio range is 14 to 20 parts of fresh-frozen fruit to one part of finished extract powder. Additional details of the manufacturing method may be found in the confidential TGA report in Appendix 2.

1.7 Stability

The powder must be stored in sealed bags to prevent contamination with atmospheric moisture and microbial organisms. The powder is sealed in double polyethylene bags placed inside a fiber drum is the standard method of warehouse storage. The product must be stored under controlled room temperature conditions. Stability test data are summarized in the confidential TGA report provided in Appendix 2.

ABG's Kakadu plum extract product must be re-tested to verify adherence to product specifications after 12 months of storage. Subsequent testing must be done every six months since vitamin C concentration may decrease over time. As a result, long-term storage (>2 years) is not recommended.

2.0 Intended Use

The intended use of Kakadu Plum Concentrate is as a natural source of Vitamin C, similar to that of acerola cherry, rose hips, and blackcurrant extracts, in dietary supplements. Kakadu Plum Concentrate is formulated to deliver 150 - 450 mg Vitamin C per gram.

3.0 Summary of Data and Information Supporting Safety

A literature search through June 11, 2004 was conducted by ABG. A total of 29 citations were found for Kakadu plum. None of these citations referred to any toxicity or adverse effects associated with the Kakadu plum. Results of the literature search are provided in Appendix 3.

Hegarty et al. (2001) analyzed Kakadu plum fruit for cyanogenic glycosides and alkaloids. Fruit from one source showed negative in the test for alkaloids. Fruit from two sources contained less than 0.1 mg HCN per 100 grams of fruit. The reported values for oxalates, cyanogens and saponins in the Kakadu Plum fruit do not exceed those recorded for widely consumed foods, Miller and Woodrow (2004); Hegarty et al. (2001). The value for alkaloids is below that of common citrus fruits, Hegarty et al. (2001). ABG's Kakadu Plum Concentrate is a water extract of the fruit; however, it is expected that this extract would have similar properties in this respect to the whole fruit.

Kakadu Plum Concentrates containing 30% (Sample 3280) and 35% Vitamin C (Sample 2939) were also analyzed for cyanogens, alkaloids and oxalate by Miller and Woodrow (2004). They reported no detectable levels of cyanogens or alkaloids, and an oxalate concentration ranging from 25 $\mu\text{g/g}^{-1}$ dry weight to 64 $\mu\text{g/g}^{-1}$ dry weight for the Kakadu Plum Concentrate samples. Based on the highest detected amount of 64 $\mu\text{g/g}^{-1}$ oxalate in Kakadu Plum Concentrate, the maximum amount of oxalate ingested would be approximately 250 micrograms/4 gram dose, or 1/2630th of the amount found in a 100g serving of spinach.

Support for safety relies on the long history of Kakadu plum as a food and the approval by the Australian TGA. Traditional use by Australian Aborigines is described by Isaac (1997). Contemporary use in products such as jams, preserves, relishes, sauces, juices and ice cream flavoring is described by Graham and Hart (1997), Woods (1998), Lindsay (2000), Vic Cherikoff Food Services (2001), Australian Food & Wine (2002) and Australian Culinary Consultants (2004). On a vitamin C basis, one gram of Kakadu Plum Concentrate containing 150 mg of Vitamin C equates to approximately 2 medium Kakadu plums.

The Australian TGA (2003) determined that there is no evidence of any toxicity associated with the traditional use of the Kakadu plum fruit and recent use of such food products. Moreover, the TGA concluded that, like the fruit, ABG's Kakadu Plum Concentrate is not expected to produce any toxicity after oral ingestion. The Australian TGA further concluded that "Kakadu Plum Concentrate appears suitable for adults, children, and pregnant and lactating women." Based on the above-described data and information, ABG has concluded that its Kakadu Plum Concentrate when used as a natural source of Vitamin C, under ordinary conditions of intended use of dietary supplements, does not present an unreasonable or significant risk to safety and is reasonably expected to be safe.

4.0 References

- Australian Culinary Consultants (2004). *Indigenous Food - Robins Bush Foods: Capturing the wild flavours of Australia*.
http://www.my-au.com/culinary/indigenous_robinsbf.htm.
- Australian Food & Wine (2002). Bushfood, Spices and Sauces, Kakadu Plum (*Terminalia ferdinandiana*). <http://www.australian-food-wine.com/en/?cat=15>.
- Graham C. and Hart D. (1997). Bushfoods. The New Rural Industries, A handbook for Farmers and Investors. Rural Industries Research & Development Corporation, Barton ACT, Australia. <http://www.rirdc.gov.au/pub/handbook/bushfoods.html>.
- Hegarty, M.P., Hegarty, E.E, Plantchem Pty Ltd and Wills, R.B.H. (2001). Food Safety of Australian Bushfoods, § 2.2.15. *Terminalia* species. RIRDC Pub. No. 01/28. Rural Industries Research & Development Corporation, New Plant Products Research and Development, Barton ACT, Australia.
- Isaac J. (1997). Bushfood. Lansdown.
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